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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH
CENTRAL DIVISION

UNITED STATES OF AMERICA, *ex rel.* RYAN CREEK, *Plaintiffs/Relators*, v. POLARITYTE, INC., and POLARITYTE MD, INC., *Defendants*.	***QUI TAM* COMPLAINT** Civil Case No. _____ Judge: _____ Date Received: _____ FILED IN CAMERA SEALED PURSUANT TO 31 U.S.C. § 3730(b)(2) **JURY TRIAL DEMAND**

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Plaintiff and *qui tam* Relator Ryan Creek, by and through his undersigned counsel Ray Quinney & Nebeker P.C. and Brown, LLC, alleges of personal knowledge as to his own observations and actions, and on information and belief as to all else, as follows:

INTRODUCTION AND NATURE OF ACTION

1. This is a *qui tam* action on behalf of the United States of America (the "Government") under the False Claims Act, 31 U.S.C. §§ 3729 *et seq.* (the "FCA"), to recover treble the actual damages sustained by, and civil penalties owed to, the Government arising from Defendants' scheme to cause the submission of false claims to Medicare.

2. Defendants PolarityTE, Inc. and PolarityTE MD, Inc., design, develop, and market a Product called SkinTE (the "Product"). Defendants' promotional materials describe the Product as "an autologous skin construct … for the repair, replacement, reconstruction, or supplementation of skin tissue and integumentary system,"[1] and as "an adjunct and/or [to be used] in place of skin grafting," *see* **Exhibit A** (SkinTE Brochure).

3. The Product is not a full-thickness skin graft. Nevertheless, Defendants instructed doctors and other healthcare providers to incorrectly code procedures using the Product as though it were a full-thickness skin graft.

4. The upcoding allowed the providers to seek and obtain higher reimbursement from Medicare than they were entitled to. Seeing this easy profit, the providers were encouraged to use the Product more frequently, thus benefitting Defendants. Thus, Defendants knowingly conspired to cause healthcare providers to present false claims to Medicare.

[1] https://www.polarityte.com/ (last accessed Sept. 10, 2020).

5. This complaint is being filed *in camera* and under seal pursuant to 31 U.S.C. § 3730(b)(2). A copy of this complaint, along with written disclosure of substantially all material evidence and information that Relator possesses, was served on the Attorney General of the United States and the United States Attorney for the District of Utah, pursuant to 31 U.S.C. § 3730(b)(2) and Fed. R. Civ. P. 4(d).

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331, because this action is brought for violations of the FCA, 31 U.S.C. § 3729 *et seq.* (as amended).

7. The Court has personal jurisdiction over Defendants because Defendants are licensed to transact and do transact business in, this District. Defendant PolarityTE, Inc. is also headquartered in this District and has carried out its fraudulent scheme in this District.

8. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b)(2), because Defendants can be found in, reside in, are licensed to do business in, and transact or have transacted business in this District, and events or omissions that give rise to these claims have occurred in this District.

9. Pursuant to 31 U.S.C. § 3731(b), this complaint is filed within the applicable statute of limitations.

NO PUBLIC DISCLOSURE; INDEPENDENT AND MATERIAL KNOWLEDGE OF VIOLATIONS OF THE FALSE CLAIMS ACT

10. Relator makes the allegations in this complaint based on his own knowledge, experience and observations.

11. Relator is the original source of the information he has given to the Government regarding Defendant's conduct and scheme to violate federal law.

12. There has been no public disclosure, relevant under 31 U.S.C. § 3730(e), of the "allegations or transactions" in this complaint; or, to the extent that any such public disclosure has been made, Relator has knowledge that is independent of and materially adds to that public disclosure.

THE PARTIES

A. Plaintiff the United States

13. Relator brings this action on behalf of Plaintiff the United States of America. At all times relevant to this Complaint, the United States, acting through the Centers for Medicare & Medicaid Services ("CMS"), which is a part of the federal Department of Health and Human Services ("HHS"), paid providers that purchased the product from Defendants and submitted claims to Medicare for reimbursement for procedures using the product.

B. Plaintiff and Relator Creek

14. Relator Ryan Creek is a citizen of the United States and, at all relevant times, has been a resident of Salt Lake County, Utah.

15. Relator was employed by Defendants from approximately July 2, 2018, until May 19, 2020, as the director of a clinical team.

16. Relator's responsibilities included training Defendants' sales and reimbursement staff to explain to providers how the Product works.

17. Relator was in regular meetings with Defendants' reimbursement staff, including the former head of reimbursement.

18. As a result, Relator has first-hand knowledge of the reimbursement strategies adopted by Defendants to drive product sales and alleged herein.

C. Defendants

19. Defendant PolarityTE, Inc. is a Delaware corporation with a principal business address of 123 North Wright Brothers Drive, Salt Lake City, Utah 84116.

20. Defendant PolarityTE MD, Inc. is a Nevada corporation with a principal business address of 123 North Wright Brothers Drive, Salt Lake City, Utah 84116. On information and belief, PolarityTE MD, Inc. is a wholly-owned subsidiary of Defendant PolarityTE, Inc.

21. On information and belief, PolarityTE, Inc. began doing business pertaining to the Product as PolarityTE, MD, Inc., sometime in 2019. The conduct alleged in this Complaint is attributable to both PolarityTE, Inc. and PolarityTE MD, Inc. (collectively, "Defendants").

THE STATUTORY FRAMEWORK

A. The False Claims Act

22. The FCA, 31 U.S.C. §§ 3729 *et seq.*, establishes liability for any "person" (natural or corporate) who, *inter alia*:

a. "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(l)(A);

b. "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," *id.* § 3729(a)(l)(B); or

c. "conspires to commit a violation of subparagraph (A) [or] (B) …." *id.* § 3729(a)(l)(C).

23. "Knowing" is defined by the FCA to include "deliberate ignorance of the truth" or "reckless disregard of the truth." *Id.* § 3729(b)(1).

24. The FCA defines "claim" to include any request for money that:

> is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government—
>
> (I) provides or has provided any portion of the money or property requested or demanded; or
>
> (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded….

Id. § 3729(b)(2)(A)(ii). Thus, the United States has a cause of action under the FCA for conspiracy to defraud the Medicare program.[2]

25. In addition to treble damages, the FCA also provides for the assessment of a civil penalty for each violation or each false claim.[3]

26. The FCA provides for payment of a percentage of the United States' recovery to a private individual who brings suit on behalf of the United States (the "Relator") under the FCA. *See* 31 U.S.C. § 3730(d).

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[2] *See, e.g., United States ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 735 (10th Cir. 2018) (holding FCA applicable to claims in violation of Medicare laws); *see also United States ex rel. Sorenson v. Wadsworth Bros. Constr. Co.*, No. 2:16-cv-875, 2019 U.S. Dist. LEXIS 95329, at *12 (D. Utah June 5, 2019) ("While the FCA does not define a conspiracy ... courts have held that general civil conspiracy principles apply to FCA conspiracy claims." (internal quotation marks and citation omitted)).

[3] 31 U.S.C. § 3729(a)(1)(G) provides a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990, Pub. L. No. 104-410, 104 Stat. 890 (1990), *amended by* the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, Pub. L. No. 114-74, 129 Stat. 599 (2015); *see* 28 U.S.C. § 2461 note. On June 19, 2020, the Department of Justice promulgated a Final Rule increasing the penalty for FCA violations occurring after November 2, 2015. For such penalties assessed after June 19, 2020, the minimum penalty is $11,665 and the maximum is $23,331. *See* 28 C.F.R. § 85.5; 85 F.R. 37005 (June 19, 2020).

B. The Medicare Program

27. The Medicare program pays for certain healthcare services provided to certain segments of the population. Entitlement to Medicare is based on age, disability, or affliction with end-stage renal disease. *See* 42 U.S.C. §§ 1395 *et seq.*

28. HHS, through CMS, administers the Medicare program.

29. Medicare is divided into four parts. As relevant here, Medicare Part A covers all inpatient hospital services, 42 U.S.C. §§ 1395c to 1395i-5, and Medicare Part B covers other medical services referred to by an eligible medical professional, 42 U.S.C. §§ 1395j to 1395w-5.

30. To receive payment under Medicare Part A or B, a provider must submit claims to the appropriate Medicare Administrative Contractor or "MAC"[4] using a CMS-1500 form. *See* Form CMS-1500.[5] The CMS-1500 form requires the provider to identify the services for which reimbursement is sought through a five-digit Current Procedural Terminology ("CPT") or Healthcare Common Procedural Coding System ("HCPCS") code. The amount of Medicare reimbursement is based on the lesser of the actual charge and a standardized fee schedule for the appropriate CPT or HCPCS code established by the Secretary of HHS.

31. The CMS-1500 form further requires the provider to make the following certification:

> In submitting this claim for payment from federal funds, I certify that: 1) the information on this form is true, accurate and complete … 4) **this claim … complies with all applicable Medicare and/or Medicaid laws, regulations, and**

[4] A MAC is a private insurer awarded a geographic jurisdiction to process medical claims for Medicare beneficiaries.

[5] *Available at* https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf (last accessed Sept. 8, 2020).

> **program instructions for payment**; [and] 5) the services on this form were medically necessary and personally furnished by me or were furnished incident to my professional service by my employee …

Id., at 2 (emphasis added).

32. A provider may also submit the electronic equivalent of this claim form, which contains a substantially similar certification.

33. CMS guidance as to electronic claims submission is found in Chapter 24 of the Medicare Claims Processing Manual, CMS Publication No. 100-04 (the "Claims Manual"). Among other things, the guidance specifies the minimum content of the enrollment form that a local MAC may use to sign up providers to submit claims electronically. Per the Claims Manual, such an enrollment form must contain, and the enrolling provider must acknowledge, at least the following statements:

> The provider agrees to the following provisions for submitting Medicare claims electronically to CMS or to CMS' A/B MACs ….
>
> * * *
>
> 7. That it will submit claims that are accurate, complete, and truthful;
>
> * * *
>
> 12. That it will acknowledge that all claims will be paid from Federal funds, that the submission of such claims is a claim for payment under the Medicare program, and that anyone who misrepresents or falsified or causes to be misrepresented or falsified any record or other information relating to that claim that is required pursuant to this agreement may, upon conviction, be subject to a fine and/or imprisonment under applicable Federal law; [and]
>
> * * *
>
> 14. That it will research and correct claim discrepancies[.]

Claims Manual, Ch. 24 § 30.2.

34. The submission of such a certification, if false, is a violation of the FCA. 31 U.S.C. § 3729(a).

35. Each such false certification is a separate violation of the FCA.

DEFENDANTS' FRAUD

36. Defendants launched their flagship product, SkinTE, in 2018.

37. The Product is manufactured from a small sample of the patient's skin, which must first be harvested from the patient and sent to Defendants' facility for production. The Product is delivered to the provider in a syringe which is then applied topically over the wound as a paste. *See* **Exhibit B** (SkinTE Instructions) at 6-15.

38. The Product was registered with the Food and Drug Administration as a human cells, tissues, and cellular and tissue-based product ("HCT/P").

39. Defendants sold the Product directly to providers, who in turn billed the cost to their patients' insurers. A large proportion of the patients for whom the Product was used were Medicare beneficiaries, who suffered from, among other things, diabetic wounds, pressure ulcers, and other skin breakdowns associated with old age. Thus, a substantial number of claims for the product were submitted to, and reimbursed by, Medicare.

40. Soon after launch, it became clear that SkinTE was not the moneymaker Defendants had hoped for: in late 2018, Defendant PolarityTE, Inc. reported a lackluster $400,000 in revenue from the Product.[6]

[6] *See* https://www.proactiveinvestors.co.uk/companies/news/212533/polarityte-prepares-for-launch-of-skinte-in-2019-posts-11m-in-revenue-in-fiscal-4q-212533.html (last accessed Sept. 8, 2020).

41. Defendants attributed the poor sales at least in part to the low Medicare reimbursement for the Product when properly coded and billed as an HCT/P product, making it unattractive to providers.

42. In 2018, CMS issued a temporary HCPCS code (Q4200) specifically for the SkinTE product,[7] and classified it in the "low-cost" category, which limited the amount of reimbursement available.

43. To inflate the reimbursement rate and increase sales, Defendants' sales staff began actively advising providers to disregard the appropriate CPT/HCPCS code and to code the Product as a full-thickness skin graft instead.

44. Defendants knew the Product was not a full-thickness skin graft.

45. Skin grafting is defined as a surgical procedure that involves removing skin from one area of the body and transferring it to a different area of the body.[8] Although synthetic and tissue-cultured grafts do exist, they are applied as a skin-like covering which is anchored over the wound area.

46. In contrast, SkinTE is applied as a paste and cannot be classified as a graft. *See* **Exhibit B** (SkinTE Instructions) at 14-15.

47. In 2019, Defendants released a reimbursement guide for providers, indicating that the Product could be coded as a full-thickness graft. *See* **Exhibit C** (SkinTE Reimbursement Guide) at 7-8.

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[7] *Available at* https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/2018-05-16-HCPCS-Application-Summary.pdf (last accessed Sept. 8, 2020).

[8] *See, e.g.*, https://www.merriam-webster.com/dictionary/skin%20graft (last accessed Sept. 9, 2020).

48. The guide highlighted to providers the significantly higher reimbursement rates they could receive if they coded the Product as a full-thickness skin graft.

49. For example, the Medicare average reimbursement rate for a full-thickness graft was $697 per 20 cm^2 at a physician facility. In comparison, the average reimbursement rate for a skin substitute was only $87.21 per 100 cm^2 in the same setting. *Id.*

50. To further increase reimbursements, Defendants' sales staff instructed providers to code the initial harvesting procedure as a full-thickness skin graft using a modifier code,[9] then to separately code the subsequent application of the Product as a second full-thickness skin graft procedure. This effectively allowed providers to bill Medicare twice for a single use of the Product.

51. Defendants' sales and reimbursement staff also provided directions on how to evade scrutiny from CMS and auditors.

52. First, Defendants advised providers not to use the Q4200 code, which CMS had created to identify procedures using the Product.

53. Second, Defendants' staff instructed providers to use specific language in patient charts and billing records so that the procedure would look like a traditional skin graft. For example, Defendants knew, from feedback from providers who used the Product, that CMS was more likely to approve claims using specific terms and phrasing, such as "placed [the graft] across the entire wound surface and fixated in place with the primary dressing," and instructed providers to state as such. *See* **Exhibit D** (Surgical Documentation Card).

[9] Modifier codes are used to supplement information concerning a procedure. They include codes 52 for reduced or partial service, and 58 for related or staged procedures. *See* **Exhibit C** at 6.

54. Defendants' fraudulent conduct was intentional. The sales and upcoding strategies alleged above were developed and refined during months of discussions among company executives, many including Relator. The strategies were an integral part of the training given to sales and reimbursement staff.

55. Likewise, providers were well aware that the Product could not legitimately be billed as a full-thickness skin graft.

56. Those providers who followed Defendants' instructions and coded and billed the Product to Medicare as a full-thickness skin graft knowingly submitted false claims for reimbursement in violation of the FCA.

57. As a result of Defendants' scheme, sales of the Product increased. Moreover, due to the higher reimbursement rate, Defendants could charge providers more for the Product. In August 2020, Defendant PolarityTE, Inc. reported almost $1 million in SkinTE revenue, more than doubling its revenue from October 2018.[10]

58. During Relator's tenure, Defendants maintained a database of provider customers which included information showing that most if not all providers sought and received reimbursement from Medicare as though the Product were a full-thickness skin graft.

59. Through the above scheme, Defendants conspired to defraud the Government by causing false or fraudulent claims to be submitted to CMS.

[10] *Available at* https://www.businesswire.com/news/home/20200806005238/en/PolarityTE-Reports-Quarter-2020-Results (last accessed Sept. 9, 2020).

CLAIM FOR RELIEF FEDERAL FALSE CLAIMS ACT: CONSPIRACY TO SUBMIT FALSE CLAIMS

60. Through the acts described above, Defendants conspired with various providers to cause false claims to be submitted to Medicare, and to cause providers to make materially false statements to the Government, in violation of 31 U.S.C. § 3729(a)(1)(A)-(C).

61. Defendants knowingly and willfully committed the above acts in furtherance of that conspiracy.

62. As a proximate result of Defendants' conduct, providers submitted false claims to Medicare, and thereby caused the Government to suffer damages by paying out monies it would not have paid if it had known that the product was fraudulently coded and billed to Medicare as a full-thickness skin graft.

PRAYER FOR RELIEF

WHEREFORE, Relator respectfully requests that this Court enter judgment in his favor and the United States, granting the following:

(A) an award to the United States for treble its damages, a civil penalty for each violation of the FCA, and its costs pursuant to 31 U.S.C. § 3729(a)(3);

(B) an award to Relator in the maximum amount permitted under 31 U.S.C. § 3730(d), and for the reasonable attorney's fees and costs he incurred in prosecuting this action;

(C) awards to the United States and Relator for pre- and post-judgment interest at the rates permitted by law; and

(D) an award of such other and further relief as this Court may deem to be just and proper.

DEMAND FOR TRIAL BY JURY

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Relator demands trial by jury on all questions of fact raised by the Complaint.

DATED this 18Th day of September, 2020

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